LIQUID AMINO ACID NUTRITIONAL COMPOSITION

This invention relates to enteral tube feeding compositions.

More particularly, the invention relates to a liquid enteral tube feeding composition which contains free amino acids and glutamine in a di-peptide form and which has extended shelf life during which glutamine will not convert in situ into glutamate.

In another respect, the invention relates to a method which, in comparison to prior art procedures, significantly reduces the cost of producing liquid enteral tube feeding composition with free amino acids because the method produces a ready-to-use liquid enteral tube feeding composition instead of the powdered feeding compositions which are now on the market and which must be reconstituted prior to use.

High amino acid—glutamine powdered enteral elemental tube feeding products are well known, and are reconstituted with water just prior to use. In the United States, the market for such products exceeds $100 million annually. Examples of enteral tube feeding products include VITAL™ and ALITRAQ™ sold by Ross, VIVONEX™ sold by Sandoz, and IMMUNAID™ marketed by McGaw. Disadvantages are associated with such powdered enteral elemental tube feeding products. First, the products are powders which must be mixed. Mixing is labor intensive, increases chances for errors, increases the risk of contamination, and is messy. Second, the products must be in powder form because the amino acid glutamine is not stable in water; it converts quickly to glutamate. This is undesirable because glutamine—and not glutamate—is generally believed to a fuel used preferentially by the gut. It is also undesirable because a high free amino acid content is preferred in enteral tube feeding products for certain critically ill patients. Third, during mixing of high amino acid—glutamine liquid enteral tube feeding products creaming out can occur.

The inability to provide a high amino acid—glutamine enteral tube feeding formula which is stable in liquid form and which does not cream out is why powdered enteral elemental tube feeding products currently dominate the market for high glutamine formulas.

Accordingly, it would be highly desirable to provide a liquid ready-to-use high amino acid enteral tube feeding formulation in which glutamine would not convert quickly to glutamate and in which the remaining protein and nutritional components would also be stable.

Therefore, it is a principal object of the invention to provide an improved enteral tube feeding formulation.

A further object of the invention is to provide an improved liquid enteral tube feeding formulation that includes glutamine and other free amino acids and that has an extended shelf life during which glutamine will not convert to glutamate.

These and other, further and more specific objects and advantages of the invention will be apparent to those skilled in the art from the following detailed description thereof.

Briefly, I have, in the first embodiment of the invention, discovered an improved liquid food composition for ingestion along the digestive tract of a patient. The food composition includes 25% to 95% by weight of water; free amino acids; glutamine; triglycerides of predominantly 6 to 26 carbon atoms in the fatty acid chain; carbohydrates selected from the group consisting of corn syrup solids, trisaccharides, tetrasaccharides, pentasaccharides, hexasaccharides, dextrose, fructose, sucrose, maltose, oligosaccharides and higher saccharides; and, a stabilizer comprising a polyglycerol ester. In a second embodiment of the invention, I have discovered a method for preparing a liquid food composition for ingestion along the digestive tract of a patient. The method includes the step of providing formula components including water; free amino acids including glutamine; triglycerides of predominantly 6 to 26 carbon atoms in the fatty acid chain; carbohydrates selected from the group consisting of corn syrup solids, trisaccharides, tetrasaccharides, pentasaccharides, hexasaccharides, dextrose, fructose, sucrose, maltose, oligosaccharides and higher saccharides; and, a stabilizer comprising a polyglycerol ester. The formula components are mixed to produce the liquid food composition.

The liquid food composition comprising the first embodiment of the invention or produced in the second embodiment of the invention can, if desired, include:

1. From 5% to 48% by weight carbohydrates, preferably 10% to 22% by weight carbohydrates.
2. Glutamine in the range of 0.5% to 8.0% by weight, preferably about 1.5% to 5.0% by weight. The glutamine is preferably in a di-peptide form which is not readily converted to glutamate. The glutainine is also preferably in the form of a protein which is high in glutamine and hydrolyzed to contain a large percentage of short chain peptides.
3. 0.5% to 5.0% by weight, preferably about 1.0 to 3.0% by weight, of free amino acids. The free amino acids include one or more of alanine, arginine, aspartic acid, cystine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methlanine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, and valine.
4. Appropriate desired levels of nutritionally required vitamins and minerals, which vitamins and minerals typically comprise 0.1% to 5.0% by weight, preferably 0.5% to 3.0% by weight of the composition.
5. Choline chloride in a concentration in the range of 0.01% to 1.0% by weight, preferably about 0.05% to 0.30% by weight.
6. Soybean oil, sunflower oil, corn oil, coconut oil or any other desired source of fat (preferably medium chain triglycerides with 6 to 26 carbon atoms in the fatty acid chain) in the range of 0.01% to 15.0% by weight, preferably 0.1% to 1.0% by weight. Soybean oil provides triglycerides of predominantly 6 to 26 carbon atoms in the fatty acid chain.

The food composition of the invention can be pasteurized or sterilized because the stabilizer(s) described below prevent precipitation of the various components of the food composition.

Discovering a stabilizer system which would prevent the precipitation of amino acids from the food composition of the first embodiment of the invention or from the food composition produced in the second embodiment of the invention was difficult, and required about one year of testing various stabilizers and stabilizer combinations. The preferred stabilizer system of the invention includes:

1. Starch, preferably potato, rice, and/or tapioca starch, in a concentration in the liquid food composition of the invention in the range of 0.05 to 2.80% by weight, preferably 0.10 to 0.50% by weight.
2. Carrageenan in a concentration in the liquid food composition of the invention in the range of 0.002% to 0.10% by weight, preferably 0.01 to 0.04% by weight. If desired, xanthan gum, locus bean gum, monodiglycerides, guar gum or other gums can be utilized in combination with or in place of carrageenan.
3. Lecithin in a concentration in the liquid food composition of the invention in the range of 0.01% to 0.25% by weight, preferably 0.05% to 0.15% by weight.